Australian Government

Department of Health

Office of the Gene Technology Regulator

OPERATIONS OF THE GENE TECHNOLOGY REGULATOR

QUARTERLY REPORT

1 JANUARY–31 MARCH 2015

The object of the *Gene Technology Act 2000* is:

'to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms'

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Inquiries about the content of this report may be directed to the Business Management and Communications Section, Regulatory Practice and Compliance Branch of the Office of the Gene Technology Regulator.

LETTER OF TRANSMITTAL

Senator the Hon Fiona Nash MP
Assistant Minister for Health
Parliament House
CANBERRA ACT 2600

Dear Minister

In accordance with section 136A of the *Gene Technology Act 2000* (the Act), I am pleased to present to you the Quarterly Report of the Operations of the Gene Technology Regulator, covering the period 1 January to 31 March 2015.

During this period two licences were issued for dealings involving intentional release of GMOs, one licence were issued for dealings not involving intentional release of GMOs, and 17 physical containment facilities were certified.

Routine monitoring activities for this quarter exceeded the target rate and no significant risks to either human health or the environment were identified.

Yours sincerely

Dr Robyn Cleland
Acting Gene Technology Regulator

10 June 2015

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ABOUT THIS REPORT

Sub-section 136A(1) of the *Gene Technology Act 2000* (the Act) requires the Gene Technology Regulator (the Regulator) to prepare and give to the Minister after each quarter a report on the operations of the Regulator during that quarter. Sub-section 136A(2) of the Act requires that the report include information on:

- GMO licences issued during the quarter
- breaches of conditions of a GMO licence that have come to the Regulator's attention during the quarter
- Emergency Dealing Determinations (EDDs) made by the Minister during the quarter
- any breaches of conditions of an EDD that have come to the Regulator's attention during the quarter
- auditing and monitoring of dealings with GMOs under the Act by the Regulator or an inspector during the quarter.

Its purpose is to inform the community of our roles and responsibilities and to provide a summary of our achievements over the past quarter.

This report has four key sections.

Gene technology regulatory system

Provides advice on the activities and outcomes achieved in relation to the implementation and management of the national regulatory system during the quarter.

Regulation of genetically modified organisms

Provides details on the regulatory activity undertaken, including information about applications for, and action taken with respect to, GMO licences and other instruments under the Act. It also includes details of monitoring, auditing and compliance activities by the Regulator during the quarter.

Statutory committee operations

Reports on the activities of the two advisory committees established under the Act to assist the Regulator and the Legislative and Governance Forum on Gene Technology.

Other activities of the Gene Technology Regulator

Describes other activities relating to the statutory functions of the Regulator that support the operations of the gene technology regulatory system.

SECTION 1

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

NATIONAL GENE TECHNOLOGY REGULATORY SYSTEM

Key achievements during this quarter

The key achievements of the 1 January to 31 March 2015 quarter were:

Licences and other instruments

- 2 licences issued for Dealings involving the Intentional Release (DIR) of GMOs into the environment
- 1 licence issued for Dealings Not involving the Intentional Release (DNIR) of GMOs into the environment
- 17 physical containment facilities certified
- 24 instruments surrendered
- 49 certifications, four DIR licences and 10 DNIR licences varied.

Further information on licences and other instruments is contained in Section 2 of this report.

Monitoring and Compliance

Approximately 15 per cent of current field trial sites and eight per cent of post-harvest field trial sites were subjected to routine monitoring during the quarter. This exceeds the target minimum rate of five per cent of all field trial sites per quarter.

Further information on monitoring and compliance is contained in Section 2 of this report.

Working collaboratively with States and Territories

Legislative and Governance Forum on Gene Technology

The Legislative and Governance Forum on Gene Technology (LGFGT) oversees the implementation of the regulatory system and comprises one Minister from the Commonwealth and one Minister from each of the States and Territories. Currently, the LGFGT includes Ministers from a range of portfolios including health, agriculture and environment.

State and Territory consultation

The Regulator must consult with State and Territory Governments and appropriate local councils during the evaluation of applications for all DIR licences.

For each application for a DIR licence other than a limited and controlled release, the Regulator is required to seek advice on matters relevant to the preparation of the Risk Assessment and Risk Management Plan (RARMP), and must also seek comment on the RARMP itself once it is prepared. For each application for a limited and controlled release, the Regulator is required to seek comment on the RARMP.

During the quarter the Regulator sought advice from State and Territory governments on matters relevant to preparing one RARMP, as well as comment on one RARMP.

Further information is contained in Section 2 of this report.

Australian Government Agency liaison

The close relationship between the OGTR and other Australian Government authorities and agencies continued during this quarter.

Under the Act, the Regulator must seek advice from the Australian Government Environment Minister, and prescribed Australian Government authorities and agencies, on matters relevant to preparing the RARMP for each application for a DIR licence, except those that meet the criteria to be considered as a limited and controlled release.

The prescribed Australian Government authorities and agencies are:

- Australian Pesticides and Veterinary Medicines Authority
- Department of Agriculture, Biosecurity
- Food Standards Australia New Zealand
- National Industrial Chemicals Notification and Assessment Scheme
- Therapeutic Goods Administration.

Once a RARMP is prepared for any DIR licence application, the Regulator is required to seek comment on the RARMP from the same prescribed Australian Government authorities and agencies.

In addition, comment is sought on each DIR RARMP from a range of other Government agencies that are not prescribed in legislation but have maintained a strong interest in gene technology regulation, including:

- Department of Agriculture, Agricultural Policy Division
- Department of Foreign Affairs and Trade.

During the quarter the Regulator sought advice from Australian government agencies on matters relevant to preparing one RARMP, as well as comment on one RARMP.

During the quarter the OGTR and the Department of Agriculture initiated a joint project to explore opportunities to harmonise by better aligning requirements for containment facilities.

Further information on the processing of DIR applications is contained in Section 2 of this report.

Public participation

The Act requires the Regulator to consult the public on the RARMPs for all DIR licence applications. One invitation to the public to comment on a RARMP was issued during the quarter. Summaries of public submissions are provided in the final RARMP.

Further information on the processing of DIR applications is contained in Section 2 of this report.

SECTION 2

REGULATION OF GENETICALLY MODIFIED ORGANISMS

REGULATION OF GENETICALLY MODIFIED ORGANISMS

Section 2 of the report outlines the regulatory activity undertaken during the 1 January 2015 to 31 March 2015 quarter. This includes information about applications for GMO licences and other instruments under the Act. This section details any EDDs made pursuant to the Act. It also includes details of monitoring activities and investigation of alleged, admitted or self-reported non-compliances with the Act, or with the conditions imposed by the Regulator on GMO licences or other instruments issued pursuant to the Act. Summary reports on investigations completed during the quarter are supplied. Information on Confidential Commercial Information (CCI) applications has also been provided.

Types of Applications

Under the Act the Regulator is required to make decisions in relation to applications for the following instruments:

Dealings involving Intentional Release licences

DIR licences authorise dealings ranging from limited and controlled releases (e.g. field trials) through to more extensive general or commercial releases. DIR licence applications have a statutory timeframe of 255 working days for making a decision unless the Regulator determines the application is a limited and controlled release application. Then the timeframe for making a decision is 150 working days, or 170 working days if the Regulator determines that the proposed dealings represent a significant risk to human health and the environment.

Dealings Not involving Intentional Release licences

DNIR licences authorise contained dealings with GMOs carried out in laboratories and other containment facilities that are designed to prevent release of the GMO(s) into the environment. These licence applications have a statutory timeframe of 90 working days for making a decision.

Accreditations of organisations

DIR and DNIR licence conditions require organisations which conduct work with GMOs to be accredited. To achieve accreditation, the Regulator must be satisfied that the organisation has, or has access to, a properly constituted and resourced Institutional Biosafety Committee (IBC) and meets the requirements of the Regulator's guidelines for accreditation. These applications have a statutory timeframe of 90 working days for making a decision.

Certifications of containment facilities

Certification is required to satisfy the Regulator that a facility which is proposed to be used to conduct dealings with a GMO meets the guideline requirements for the particular level of physical containment specified. These applications have a statutory timeframe of 90 working days for making a decision.

GMO Register

The GMO Register is a list of dealings with GMOs that the Regulator is satisfied pose minimal risks to human health and safety and the environment and can therefore be undertaken by anyone, subject to any specified conditions, without the oversight of a licence holder. Under section 78 of the Act the Regulator may determine that dealings with a GMO previously authorised by a licence are to be included on the GMO Register. Such determinations are disallowable instruments.

New licences and other instruments

The following table describes the number and type of applications received for new licences and other instruments, as well as the approvals made by the Regulator in the quarter.

Application type	Number received	Number approved*
Accreditation	5	0
DIR licence	4	2
DNIR licence	2	1
Certifications	17	17

* *Approvals reported in the current quarter often relate to applications received in previous quarters.*

Processing of applications for Dealings involving Intentional Release licences

The key steps the Regulator takes when considering an application for a DIR licence are:

- initial screening of the application for completeness
- determining whether or not the application is a limited and controlled release
- considering the applicant's suitability to hold a licence, having regard to relevant convictions, revocations and suspensions of related licences and permits, and ability to meet conditions of the licence
- seeking comments from prescribed experts, agencies and authorities on issues to consider in the RARMP for all DIR applications except limited and controlled releases
- preparing a consultation RARMP, including proposed licence conditions to manage risks to human health and safety and the environment, and determining whether the proposed dealings may pose a significant risk
- seeking comments on the RARMP from prescribed experts, agencies and authorities and the public

- considering all comments relating to the protection of human health and safety and the environment in finalising the RARMP
- confirming the applicant's suitability, including their capacity to meet licence conditions, and considering policy principles and any relevant policy guidelines issued by the LGFGT.

Once these actions are completed, the Regulator can make a decision on whether or not to grant a licence and the conditions which are to be included in the licence if issued.

The statutory timeframes for making decisions on DIR licences effectively extend over approximately 12 months, and eight or nine months for limited and controlled releases, as they exclude weekends and public holidays observed in the Australian Capital Territory.

This time limit may be extended, that is, the clock may be stopped, if the decision-making process is unable to continue, for example, because additional information is sought from the applicant.

The Act and the Gene Technology Regulations 2001 (the Regulations) mandate a minimum timeframe for public consultation on the RARMP of 30 days, or 50 days if the Regulator identifies a significant risk to people or the environment from the proposed dealings. However, consultation periods longer than minimum timeframes are usually allowed to facilitate the provision of information and promote involvement in the decision-making process, particularly by the community. The following table shows the progress of applications for DIR licences undergoing evaluation during the quarter.

Applications received	Notifications of applications*	Consultation on application	Consultation on RARMP	Licences issued
DIR 135	DIR 134	DIR 134	DIR 133	DIR 130
DIR 136	DIR 135			DIR 131
DIR 137	DIR 136			
DIR 138				

* *Although not required under the Act, all new limited and controlled release DIR applications are notified on the OGTR website under 'What's New' and notified to all individuals and organisations on the OGTR mailing list*

Applications received for Dealings involving Intentional Release

The Regulator received four applications for DIR licences in the quarter:

- DIR 135—GM Sugarcane (The University of Queensland) Limited and controlled release of sugarcane genetically modified for enhanced sugar content
- DIR 136—GM Cotton (CSIRO) Limited and controlled release of cotton genetically modified for enhanced fibre quality
- DIR 137—GM influenza (AstraZeneca Australia Pty Ltd) Commercial supply of attenuated GM influenza vaccines
- DIR 138—GM Canola (Bayer CropScience Pty Ltd) Commercial release of canola genetically modified for herbicide tolerance and a hybrid breeding system.

Consultation on applications and consultation on RARMPs for Dealings involving Intentional Release

Although not required by the Act, the Regulator issued a 'Notification of Licence Application' for one commercial and two limited and controlled DIR licence applications. These notifications were posted on the OGTR website and sent to people and organisations on the OGTR mailing list to advise receipt of the applications and indicate when the RARMPs are expected to be released for public comment:

- DIR-134—GM Carnation (International Flower Developments Pty Ltd) Commercial import and distribution of GM carnations with altered flower colour
- DIR-135—GM Sugarcane (The University of Queensland) Limited and controlled release of sugarcane genetically modified for enhanced sugar content
- DIR-136—GM Cotton (CSIRO) Limited and controlled release of cotton genetically modified for enhanced fibre quality.

Consultation with expert groups and key stakeholders took place as part of the process to identify risks to human health and safety or the environment to be considered in preparing the RARMP for the following application:

- DIR-134—GM Carnation (International Flower Developments Pty Ltd) Commercial import and distribution of GM carnations with altered flower colour.

There was one invitation to comment on a RARMP issued during the quarter:

- DIR-133—GM Cotton (Bayer CropScience Pty Ltd) Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance.

Full copies of DIR applications can be obtained by contacting the OGTR. Summary information on DIR applications and full RARMPs, including proposed licence conditions, are available via the OGTR website or directly from the OGTR.

Withdrawn applications and surrendered licences for Dealings involving Intentional Release

One DIR licence was surrendered during the quarter:

- DIR 105—GM Canola (Monsanto Australia Limited) Limited and controlled release of canola genetically modified for herbicide tolerance.

Clock stopped on licence applications for Dealings involving Intentional Release

The Regulations determine that a day on which the Regulator is unable to proceed with the decision-making process, or a related function, because information requested from the applicant has not been received, is not counted as part of the prescribed timeframe for making a decision on an application.

The clock was not stopped on any DIR applications in this quarter.

Decisions on applications for Dealings involving Intentional Release

Two DIR licences were issued during the quarter.

- DIR 130—GM Wheat (Murdoch University) Limited and controlled release of wheat genetically modified for improved grain quality
- DIR 131—GM Safflower (CSIRO) Limited and controlled release of safflower modified for high oleic acid composition.

Information on DIR applications, finalised RARMPs, licences issued and copies of licences are available from the OGTR website or can be obtained by contacting the OGTR directly.

Decisions on applications for Dealings Not involving Intentional Release

These dealings must be conducted in appropriate containment facilities and the dealings must not involve intentional release of a GMO into the environment.

One DNIR licence was issued during the quarter:

- DNIR 554—(QIMR Berghofer Medical Research Institute) Production and clinical trial of a genetically modified *Plasmodium falciparum* blood stage vaccine.

A full listing of DNIR licences and their current status is available from the OGTR website.

Changes to existing licences and other instruments

The Regulator can, directly or upon request, vary an issued licence or other instrument. Variations involve changes to conditions applied to an instrument or a licence. For example, the Regulator can vary a licence to manage risks if new information or data comes to light. The Regulator must not vary the licence unless satisfied that any risks posed by the dealings, proposed to be authorised by the licence as varied, are able to be managed in such a way as to protect the health and safety of people and the environment.

Most variations are made at the request of the instrument/licence holder. Applications for variation to licences have a statutory timeframe of 90 days for making a decision. Additionally, the Regulator can make a decision in relation to an application to transfer a licence/instrument to another person or consent to the surrender of a licence/instrument on request by a licence/instrument holder.

The following table describes the number and type of applications for variation and surrender received in relation to existing licences and other instruments, as well as the number of variations and surrenders approved during the quarter.

Type	Number received	Number approved[a]
Surrender of accreditations	2	2
Surrender of certification	17	21
Surrender of DIR licence	5	1
Surrender of DNIR licence	0	0
Variation of accreditation	0	0
Variation of certification	48	49
Variation of DIR licence	3	4
Variation of DNIR licence	9	10

[a] *Numbers reported in this quarter often relate to applications received in previous quarters.*

Emergency Dealing Determinations

During this quarter the Regulator did not receive any requests for advice in relation to the making of any Emergency Dealing Determinations (EDD) and no EDDs were in effect.

Confidential Commercial Information

Under section 184 of the Act a person may apply to the Regulator for specified information to be declared confidential commercial information (CCI) in accordance with section 185 of the Act. Specified information awaiting a decision on an application for CCI is treated as if it were CCI until a decision is made. If the Regulator declares information to be CCI the information is protected from disclosure. More information on the protection of CCI is available on the OGTR website.

During the quarter, the Regulator received three CCI applications. The Regulator made three CCI declarations during the quarter.

Monitoring and Compliance

The aim of OGTR monitoring and compliance activities is to ensure that dealings with GMOs comply with legislative obligations and are consistent with the object of the Act:

> *'to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs'.*

In particular, the Monitoring and Compliance Sections focus on management of dealings at field trial sites and within containment facilities certified by the Regulator to ensure:

- the dissemination of a GMO and its genetic material is restricted
- the persistence of a GMO in the environment is restricted
- the containment of GMOs for dealings not involving intentional release
- effective management of the GMO is maintained.

OGTR monitoring activities comprise the functions of routine monitoring including spot checks, assessment of monitoring findings and, where necessary, recommending corrective action and follow-up activities.

OGTR compliance activities comprise reviews of potential compliance risks, investigations, audits and related enforcement activities.

Monitoring and Compliance Strategy

The Monitoring Section conducts routine inspections of field trials and contained dealings to ensure compliance with licence conditions. These inspections include announced inspections and unannounced spot checks.

The OGTR strategy for conducting monitoring draws on accumulated operational experience of risk profiling in relation to compliance.

For example, OGTR field trial monitoring coincides, where possible, with periods or circumstances when non-compliance with licence conditions designed to restrict the spread and persistence of the GMOs is more likely to occur (for example, during flowering and harvest of GM crops). Post-harvest monitoring continues until the site is free of volunteers.

A minimum of 20 per cent of field trial sites are inspected each year. To achieve this goal a minimum of five per cent of current trial sites and five per cent of trial sites subject to post-harvest monitoring are monitored each quarter.

The monitoring program for contained dealings involves inspecting DNIRs and the facilities that those dealings are conducted in. These inspections focus on the integrity of the physical structure of the facility and on the general laboratory practices followed in that facility, including those practices followed for DNIRs and Notifiable Low Risk Dealings (NLRD). Inspections are conducted on a minimum of 20 per cent of PC2 large-scale, PC3 and PC4 facilities per year.

Total field trial sites monitored: During the quarter, ten GM plant field trial sites under DIR licences were subjected to monitoring visits:

- **Current field trial sites:** Of the 39 sites current in the quarter, six were monitored. This represents a monitoring rate of 15 per cent of all current sites for the quarter
- **Post-harvest field trial sites:** Of the 49 sites subject to post-harvest monitoring in the quarter, four were monitored. This represents a monitoring rate of eight per cent of all sites subject to post-harvest monitoring in this quarter.

Monitoring of certified facilities: Monitoring in connection with contained dealings covered four organisations and 11 certified facilities. Monitoring of certified facilities encompassed three PC2 laboratories, one PC2 animal facility, one PC3 invertebrate facility, four PC3 laboratories, one PC3 animal facility and one PC4 facility

Monitoring of contained dealings: During the quarter, the monitoring of the 11 certified facilities mentioned above included monitoring of DNIRs for compliance with licence conditions that must be followed when undertaking dealings that are required to be conducted within contained facilities.

Two DNIRs were monitored during the quarter.

Monitoring of GMO Dealings involving Intentional Release

The following table summarises monitoring activities for field trials with GM crop plants for the quarter.

Licensed Organisation Name/Location of trial site	Licence Number	No. sites visited	Site status	Crop type
Bayer CropScience Pty Ltd, Queensland	DIR 113	4	2 PHM 2 Current	Cotton
Monsanto Australia Limited, Queensland	DIR 120	1	Current	Cotton
CSIRO, New South Wales	DIR 099	1	PHM	Wheat and Barley
	DIR 115	2	1 PHM 1Current	Cotton
	DIR 121	1	Current	Safflower
Monsanto Australia Limited, New South Wales	DIR 120	1	Current	Cotton
Total		**10**	**Current = 6** **PHM* = 4**	

* *PHM = post harvest monitoring*

Monitoring of Dealings Not involving Intentional Release

The following table summarises monitoring activities for DNIRs for the quarter.

Licensed Organisation Name	Licence Number
The University of Melbourne, Victoria	DNIR 527
Queensland University of Technology, Queensland	DNIR 539
Total	**2**

Monitoring of Physical Containment Facilities

The organisations and the facility types that the OGTR visited during the quarter are detailed in the following table.

Organisation	Physical Containment (PC) facility	No. facilities visited
The University of Melbourne, Victoria	PC2 Animal Facility	1
Department of Environment and Primary Industries, Victoria	PC3 Laboratory	2
CSIRO, Victoria	PC3 Invertebrate Facility	1
	PC4 Facility	1
	PC3 Laboratory	1
	PC2 Laboratory	2
	PC3 Animal Facility	1
Queensland University of Technology, Queensland	PC2 laboratory	1
	PC3 Laboratory	1
Total		**11**

Monitoring Findings

Dealings involving Intentional Release

The monitoring findings listed below indicate the monitoring activities of the OGTR with respect to dealings with GMOs, in accordance with paragraph 136A(2)(c) of the Act, and the Regulator's response to those findings.

Findings by inspectors of inconsistencies between an event or state of affairs and the requirements imposed by licence or certification conditions are called non-compliances in this report. However, non-compliances are not regarded as breaches of licence conditions unless proven to be so after investigation. Non-compliances with licence conditions are assessed against a number of considerations before determining the OGTR response. The following aspects of the findings are taken into account as relevant:

- the extent of risk to the health and safety of people and the environment
- the severity of the issue or event involved in the finding
- the culpability of the licence holder or other relevant persons in bringing about the issue or event e.g. whether there was a bona fide mistake involved
- the types of mechanisms available to address the issue or event
- the compliance history of the licence holder or other relevant persons
- mitigating factors such as self-reporting or steps taken voluntarily by the licence holder to address the issue or event
- the need for deterrence.

After having regard to those matters, the OGTR has a range of options including additional investigation to determine if further action is warranted e.g. a recommendation of prosecution for an alleged breach of a licence condition or that a licence be suspended or cancelled. A proven breach of a licence condition will be reported in accordance with paragraph 136A (2)(b) of the Act.

In the case of all matters reported below it was decided that the findings of non-compliances with licence conditions were minor in nature, involved negligible or nil culpability, and could be resolved by reminders, education and/or cooperative compliance.

Findings for Dealings involving Intentional Release

The OGTR's monitoring of DIRs in the quarter identified no non-compliances. However, there was one non-compliance issue observed for DIRs in the previous quarter that was finalised in this quarter.

Organisation	University of Adelaide
Licence number and site	DIR 102 Site 2
Summary of dealing	Limited and controlled release of wheat and barley genetically modified for abiotic stress tolerance
Findings	The University of Adelaide self-reported the unintentional planting of a related species (barley) within the isolation zone, while GMOs were growing on the site. While planting commercial barley in a field surrounding a site, the boundary of the isolation zone was incorrectly identified. As a result commercial barley was planted 10–15 metres inside the isolation zone. Despite routine monitoring being undertaken, the University of Adelaide did not identify (and destroy) the barley within the isolation zone until after it had flowered.
Assessment	Testing undertaken by the University of Adelaide of the commercial barley within the isolation zone did not find any of the GM traits authorised by this licence. As a precautionary measure the University of Adelaide harvested and destroyed all commercial barley within the isolation zone as if it were GM. The risks to human health and safety are negligible.
Compliance management	The University of Adelaide is to review its procedures and training with regards to managing the presence of related species in the isolation zone.

Findings for GMO Dealings Not involving Intentional Release

The OGTR's monitoring of DNIRs in the quarter identified no non-compliance issues with licence conditions. However, one non-compliance issue with licence conditions was identified in the previous quarter that was finalised in this quarter.

Organisation	University of Canberra
Licence number and site	DNIR 478
Summary of dealing	The proposed dealings are to introduce an interferon gene into the genome of Murray Valley encephalitis virus or chimeric Murray Valley encephalitis virus that has had two structural genes replaced with those of Dengue virus, with an aim to create interferon-adjuvanted flavivirus vaccines.
Findings	1. At the time of the inspection the University of Canberra notified inspectors that dealings with GMOs had been undertaken in a facility that had not been authorised by the licence. 2. The University of Canberra did not obtain signed statements from all persons, prior to their commencing dealings, indicating that they understood and agreed to be bound by licence conditions.
Assessment	Although not authorised by the licence, the facility in question was certified by OGTR to PC2 level as was appropriate for the dealings that were undertaken in it. Inspectors were told that the staff members had read and were familiar with the licence, but had just not signed a declaration stating that they understood and agreed to be bound by licence conditions. The risks to human health and safety and the environment have been assessed as negligible.
Compliance management	The University of Canberra is reminded of the requirement to: 1. Only undertake dealings with GMOs in facilities authorised by the licence; and 2. Obtain a signed statement from each person covered by the licence acknowledging that they have understood and agreed to be bound by licence conditions.

Findings for Physical Containment Facilities

The OGTR's monitoring of certified PC facilities in the quarter found no non-compliances with certification conditions.

	Non-Compliance Issue					
Number of PC Facilities inspected	Structure	PPE[1]	Equipment	Waste disposal	Work practices[2]	Transport
11	-	-	-	-	-	-

1 *PPE = Personal Protective Equipment.*

2 *Work practices include personnel training, record keeping, or other actions affecting compliance with certification instruments.*

Practice Reviews

The OGTR may initiate Practice Reviews in response to observations made during monitoring activities, or to follow up incident reports that may relate to non-compliance with licence conditions by accredited organisations. Their objective is to determine if licence conditions can be, and are being, effectively implemented.

An accredited organisation may request a Practice Review to assess the effectiveness of systems used by its IBC(s) to ensure that dealings are being conducted in accordance with the Act.

The primary focus of the review process is to determine whether or not practices being used pose potential human health or environmental risks that require implementation of any management actions. In certain instances, where a suspected non-compliance with the Act is identified, the issue may be referred for investigation.

There were no practice reviews completed in the quarter.

Audits

Audits can be initiated by the OGTR or an accredited organisation. An audit can entail:

- documentary evidence
- observations
- assessments of procedures and practices.

These activities are conducted to:

- verify that an accredited organisation has relevant and effective management procedures and practices to meet requirements under the Act, including accreditation requirements, guidelines and any licence conditions applicable to a dealing under the Act
- assess whether or not procedures and practices provide mechanisms to identify and resolve emerging risks
- where appropriate suggest improvements to procedures and practices.

Audits are an opportunity for accredited organisations and the OGTR to share information to improve the risk management of dealings with GMOs under the Act. Audits may focus on a single dealing, a range of dealings (e.g. dealings with a common host organism or dealings within a common climatic zone), the activity of an organisation across a range of dealings, or an activity common to a range of organisations.

There were no audits completed in the quarter.

Investigations

An investigation is an inquiry into a suspected non-compliance with the Act and corresponding state laws with the aim of gathering evidence. Such investigations are not restricted to purely criminal aspects in the wider context they may include advice on detected flaws and vulnerability in policies, practices and procedures. An investigation may be initiated: as a consequence of monitoring by the OGTR; self-reporting by an accredited organisation; or by third party reporting.

There were no investigations completed in the quarter.

SECTION 3

STATUTORY COMMITTEE OPERATIONS

STATUTORY COMMITTEE OPERATIONS

The Act establishes two committees to provide advice to the Regulator and the Legislative and Governance Forum on Gene Technology (LGFGT):

- Gene Technology Technical Advisory Committee (GTTAC)
- Gene Technology Ethics and Community Consultative Committee (GTECCC).

Committee appointments 2014–17 Appointments to GTECCC are currently under consideration by the Government.

Gene Technology Technical Advisory Committee

The function of the GTTAC under the Act is to provide scientific and technical advice, on the request of the Regulator or LGFGT on gene technology, GMOs, GM products, applications made under the Act, the biosafety aspects of gene technology and the need for policy principles, policy guidelines, codes of practice, technical and procedural guidelines in relation to GMOs and GM products and the content of such principles and codes.

GTTAC met on 29 January 2015 by video conference.

Further information about the work of GTTAC is available from the OGTR website www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gttac-2

Gene Technology Ethics and Community Consultative Committee

The function of GTECCC under the Act is to provide advice, on the request of the Regulator or the LGFGT on: ethical issues relating to gene technology; the need for and content of policy principles, policy guidelines, codes of practice; community consultation processes and risk communication for environmental release of GMOs; and matters of general concern in relation to GMOs.

There were no meetings of GTECCC during this period.

Further information about the work of GTECCC is available from the OGTR website www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gteccc-2

SECTION 4

OTHER ACTIVITIES OF THE GENE TECHNOLOGY REGULATOR

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International collaboration and coordination

Under the Act the Regulator's functions include:

- monitoring international practice in relation to regulation of GMOs
- maintaining links with international organisations that deal with the regulation of gene technology and with agencies that regulate GMOs in countries outside Australia
- promoting the harmonisation of risk assessments relating to GMOs and GM products by regulatory agencies.

International collaboration and coordination activities undertaken during the quarter included:

- Visit by a delegation of regulatory officials from South Korea, March 2015
- Visit by delegation from Japan, March 2015
- Meeting with a delegate from the New Zealand Ministry for the Environment, March 2015.

National collaboration and coordination

The Regulator and the OGTR endeavour to participate in events that inform stakeholders, the Australian community and/or users about the regulatory system.

The OGTR provided a presentation to the following:

- Regulatory Science Network meetings, Canberra, March 2015
- University of Queensland Occupational Health and Safety Forum 2015, Brisbane, March 2015.

OGTR website usage and statistics

The OGTR website is a comprehensive source of information on activities of the office. The table below provides information on the number of hits on the OGTR website and the number of visitor sessions by month during the quarter.

MONTH	HITS[1]	VISITS[2]
January	288,424	41,086
February	313,950	44,574
March	313,641	44,087

[1] *A hit is a request made to the server. Each file that is requested is counted as a hit*

[2] *Visits is the number of times the OGTR website has been visited.*

The most popular pages viewed on the OGTR website during the period were:

- Maps of Trial Sites
- List of applications and licences for Dealings involving Intentional Release (DIR) of GMOs into the environment
- Guidelines and forms for Certification of Physical Containment Facilities
- List of Genetically Modified Product approvals
- What's New
- Legislation
- Record of GMOs and GM Product Dealings
- About the OGTR
- Risk Assessment References
- What are Notifiable Low Risk Dealings (NLRDs)?

The most popular downloaded documents were:

- The Biology of *Musa* L. (banana)
- The Biology of *Saccharum spp* (Sugarcane)
- *Risk Analysis Framework*
- Guidelines for Certification of a Physical Containment Level 2 Laboratory
- The Biology of *Gossypium hirsutum* L. and *Gossypium barbadense* L. (Cotton)
- The Biology and Ecology of Rice (*Oryza sativa* L.) in Australia
- The Biology of *Zea mays* L. *ssp mays* (maize or corn)
- The Biology of *Ananas comosus* var. *comosus* (Pineapple)
- The Biology of *Carica papaya* L. (papaya, papaw, paw paw)
- The Biology of Hybrid Tea Rose (*Rosa* x *hybrida*)

Internet contacts and freecall number

OGTR email address and freecall number

The OGTR's 1800 number and email address are points of contact for members of the public and other interested parties to obtain information about the regulation of GMOs. Assistance with specific questions and additional mechanisms for public feedback are among some of the services provided by the 1800 line and email facilities. The table below describes the activity of these facilities throughout the quarter.

MONTH	EMAILS	OGTR 1800 NUMBER
January	50	46
February	69	60
March	135	50

Monitoring and compliance email inbox

The OGTR maintains an email inbox to provide a central point for accredited organisations to contact the OGTR regarding monitoring and compliance matters, such as queries, notifications required under licences, and self reporting of non-compliances. The email inbox ensures that all communications are answered efficiently while monitoring staff are away from the office. The inbox received 350 emails during the quarter.

Statutory Committee email inbox

The Regulatory Practice and Secretariat Section maintain an email inbox to facilitate efficient communication between committee members and secretariat staff.

The inbox ensures that all communications are answered in a timely manner by secretariat staff. The inbox received 160 emails during the quarter.

Application Entry Point email inbox

This electronic mail inbox provides a central, shared communication point to allow efficient coordination of responses for correspondence and queries about applications received by the Application Entry Point. The inbox received 240 emails during the quarter.

Contained Dealings Evaluation Section email inbox

This email inbox provides a central common point for efficient coordination of responses to queries relating to classification of GMO dealings, certification requirements for higher level containment facilities and GMO licences accessed by the contained dealings evaluation section. The inbox received 151 emails during the quarter.

Total emails received by OGTR during the quarter, 1,155.

GLOSSARY

This section contains a brief description of terms relevant to an understanding of this quarterly report. They do not substitute for definitions of terms relevant to the operation of the gene technology regulatory system that are contained in section 10 of the *Gene Technology Act 2000.*

Accredited organisation	An organisation that is accredited under section 92 of the Act
Act	*Gene Technology Act 2000*
APVMA	Australian Pesticides and Veterinary Medicines Authority
Breach of a licence condition	A breach of a licence condition which has been proven either in court or by way of admission following investigation
CCI	Confidential commercial information
Certified facility	A building or place certified by the Regulator to a specified containment level under section 84 of the Act
Clock stop	The period during which days are not counted for purposes of the statutory time limit for making a decision—usually because evaluation cannot proceed until additional information requested from the applicant is received
CSIRO	Commonwealth Scientific and Industrial Research Organisation
Current	In relation to a field trial location (planted under a DIR Licence) refers to a location that has been planted with a GMO and has not yet been harvested.
DIR	A dealing involving intentional release of a GMO into the environment (e.g., field trial or commercial release)
DNIR	A contained dealing with a GMO not involving intentional release of the GMO into the environment (e.g. experiments in a certified facility such as a laboratory)
Expert advisers	Advisers appointed by the Minister to give expert advice to either GTTAC or GTECCC to assist them in the performance of their functions (expert advisers are not committee members)
EDD	Emergency Dealing Determination
FSANZ	Food Standards Australia New Zealand
GM	Genetically modified
GM product	A thing (other than a GMO) derived or produced from a GMO
GMO	Genetically modified organism
GTECCC	Gene Technology Ethics and Community Consultative Committee
GTSC	Gene Technology Standing Committee
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional Biosafety Committee

Incident	A self-reported event which may constitute a non-compliance with regulatory requirements and a public health or environment risk
LGFGT	Legislative and Governance Forum on Gene Technology
Limited and controlled release	A type of DIR which meets certain criteria relating to limiting and controlling the dealings with the GMO (e.g. a field trial)
NLRD	Notifiable low risk dealing (work with transgenic plants, animals or microorganisms undertaken in certified containment facilities)
Non-compliance	An inconsistency between an event or state of affairs and the requirements imposed by licence accreditation or certification conditions, or any of the requirements of the Act or Regulations
OGTR	Office of the Gene Technology Regulator
PC1, PC2, PC3, PC4	Physical containment levels of facilities as certified by the Regulator
PHM	Post-harvest monitoring—in relation to a field trial location (planted under a DIR Licence) refers to a location that has been harvested but is still subject to regular monitoring by the licence holder
RARMP	Risk assessment and risk management plan
Regulations	Gene Technology Regulations 2001
Regulator	Gene Technology Regulator
Spot checks	Unannounced visits by the OGTR Monitoring or Compliance Sections
Volunteer	Regrowth of plants or other plant parts e.g. sugarcane that has remained on a site after a trial has been completed

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